UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Marie Kaatz and Abigail Gagliardi, individually on behalf of themselves and all others similarly situated, Plaintiffs, v. Hyland's, Inc., Standard Homeopathic Company, and John Does 1-25, Defendants.	:	Case No. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs, Marie Kaatz and Abigail Gagliardi, individually and on behalf of all others similarly situated, by their attorneys, allege the following upon information and belief, except for those allegations pertaining to Plaintiffs, which are based on personal knowledge:

NATURE OF THE ACTION

1. This action seeks to remedy the deceptive and misleading business practices of Hyland's, Inc. (hereinafter "Hyland's"), its parent company Standard Homeopathic Company (hereinafter "Standard Homeopathic"), and John Does 1-25 (collectively "Defendants") with respect to the marketing and sales of a number of their homeopathic products, including Hyland's Baby Teething Gel, Hyland's Baby Cough Syrup, Hyland's Baby Gas Drops, Hyland's Baby Infant Earache Drops, and Hyland's Baby Nighttime Tiny Cold Syrup (hereinafter collectively referred to as "Products" or "the Products").

2. Throughout the Class Period (defined below) Defendants have manufactured, sold and distributed the Products using a marketing and advertising campaign that is centered around claims that they provide "safe and effective," "fast relief," and "natural relief" from a variety of

ailments afflicting babies. However, Defendants' advertising and marketing campaign is false and misleading because the formulation in the subject products contain no relevant ingredients and because every reliable study of homeopathy has demonstrated that it does not provide any benefits beyond that of a placebo. Additionally, and contrary to Defendant's advertising, the Products are not "natural" and contain various artificial and synthetic ingredients, some of which are associated with the development of severe health problems.

3. Plaintiffs and those similarly situated ("Class Members") relied on Defendants' representations that their homeopathic Products are safe, effective and natural. Because of these representations, Plaintiffs and Class Members paid a premium for the Products over comparable products that are not represented as being safe, effective, homeopathic remedies that provide natural and fast relief from the ailments for which each of the Products is marketed and sold. Given that Plaintiffs and Class Members paid a premium for the Products based on Defendants' misrepresentations, Plaintiffs and Class Members suffered an injury in the amount of the premium paid.

4. Defendants' conduct violated and continues to violate New York General Business Law §§ 349 and 350, the consumer protection statutes of all 50 states, and the Magnuson-Moss Warranty Act. Defendants breached and continue to breach their warranties regarding the Products. Defendants' misrepresentations were negligent and Defendants have been and continue to be unjustly enriched. Accordingly, Plaintiffs bring this action against Defendants on behalf of themselves and Class Members who purchased the Products during the applicable statute of limitations period (the "Class Period").

JURISDICTION AND VENUE

5. Jurisdiction is proper pursuant to 28 U.S.C. § 1332(d)(2). Plaintiff Marie Kaatz is a citizen of the State of New York and resides in Dutchess County. Plaintiff Abigail Gagliardi is a citizen of the State of New York and resides in Dutchess County. Hyland's Inc. is a corporation with its principal place of business in Los Angeles, California, and is organized and existing under the laws of the State of California. Standard Homeopathic Company is a Nevada corporation and maintains its principal place of business in Los Angeles, California. Upon information and belief, the amount in controversy is in excess of $5,000,000, exclusive of interests and costs.

6. This Court has personal jurisdiction over Defendants because Defendants conduct and transact business in the State of New York, contract to supply goods within the State of New York, and supply goods within the State of New York.

7. Venue is proper because Plaintiffs and many Class Members reside in the Southern District of New York and Defendants sell the Products throughout the Southern District of New York.

PARTIES

Plaintiff

8. Plaintiff Marie Kaatz is an individual consumer who, at all times material hereto, was a citizen of New York residing in Dutchess County. During the Class Period Ms. Kaatz purchased the Products online.

9. Plaintiff Abigail Gagliardi is an individual consumer who, at all times material hereto, was a citizen of New York residing in Dutchess County. During the Class Period Ms. Gagliardi purchased the Products online and at retail stores.

10. Plaintiffs purchased the Products at a premium price because they saw the labeling, advertising, and read the packaging, which represented that the Products were homeopathic and provide "natural relief" for the above mentioned ailments and symptoms for which each of the Products is marketed and sold. Plaintiffs relied on Defendants' false, misleading, and deceptive representations about the Products. Had Plaintiffs known the truth—that the representations they relied upon in making their purchase were false, misleading, and deceptive—they would not have purchased the Products at a premium price. Plaintiffs would purchase the Products again if their ingredients were changed so that they truly provided "natural and fast relief" from the above mentioned ailments and symptoms for which each is marketed and sold.

Defendants

11. Defendant Hyland's Inc. is a corporation organized and existing under the laws of the State of California, with its principal place of business in Los Angeles, California. Hyland's, Inc. manufactures, markets, advertises and distributes the Products throughout the United States. Hyland's Inc. created and/or authorized the false, misleading and deceptive advertisements, packaging and labeling for the Products.

12. Defendant Standard Homeopathic Company is a Nevada corporation and the parent corporation of Hyland's, Inc., and maintains its principal place of business in Los Angeles, California.

13. Plaintiffs do not know the true names or capacities of the persons or entities sued herein as John Does 1-25 (the "DOE Defendants"), inclusive, and therefore sue these DOE Defendants by such fictitious names. Plaintiffs are informed and believe, and upon such information and belief allege, that each of the DOE Defendants is in some manner responsible

for having sold and/or advertised and/or marketed the Products and are legally responsible for the damages suffered by Plaintiffs and the members of the Class as alleged herein. Plaintiffs will amend this Complaint to set forth the true names and capacities of the DOE Defendants when they have been ascertained, along with appropriate charging allegations, as may be necessary.

14. Defendants manufacture, market, advertise and distribute the Products throughout the United States. Defendants created and/or authorized the false, misleading and deceptive advertisements, packaging and labeling for the Products.

15. At all times herein mentioned, Defendants, and each of them, were the alter egos, agents, principals, partners, members, associates, servants, employees, and subsidiaries of each of the remaining Defendants, and were at all times acting within the purpose and scope of such agency, service, and employment and directed, consented, ratified, permitted, encouraged, and approved committing the alleged acts and/or omissions of each remaining Defendant in their representative and respective relationship.

FACTUAL BACKGROUND

The Market for Homeopathic Remedies

16. American consumers are health conscious and are increasingly expressing a preference for homeopathic, natural remedies for a variety of ailments. Perceiving such remedies as safer and healthier than conventional, mainstream medicine – consumers purchase purportedly natural, homeopathic remedies to promote good health and to avoid the known and unknown dangers associated with conventional medicine and its synthetic ingredients.[1] Sales of

[1] Diskin, Colleen, *Parents Look to Homeopathy as Alternative to Over-the-Counter Cold Medicines*, NORTH JERSEY, (Dec. 19, 2010), http://www.northjersey.com/news/over-the-counter-alternatives-1.201021?page=1 (last accessed Dec. 7, 2015); *Chemical Blessings What Rousseau Got Wrong*, THE ECONOMIST, Feb. 4, 2008, available at http://www.economist.com/node/10633398; *see also* Hunger Oatman-Standford, *What Were We Thinking? The Top 10 Most Dangerous Ads*, COLLECTORS WEEKLY (Aug. 22, 2012), http://www.collectorsweekly.com/articles/the-top-

natural and homeopathic products have grown substantially in the past decade and exceed $1 billion each year.[2]

17. Defendants have helped to shape consumers' beliefs that homeopathic products are a safer, effective, natural alternative to mainstream, conventional medicine. Defendants have undertaken an aggressive marketing campaign to convince consumers of these supposed benefits of its homeopathic remedies.

18. For example, in an August 2011 press release, Defendants made the following representations about Hyland's Baby Cough Syrup:

> Parents seeking a safe, effective medicine to soothe seasonal coughs will welcome the launch of Hyland Inc.'s new Hyland's Baby Cough Syrup for infants 6 months and older. Following the FDA's 2008 warning about the use of over-the-counter medicines for infant coughs and colds due to safety concerns for very young children, parents have had few other over-the-counter medicine options to ease their children's discomfort. Hyland's new, 100 percent natural, homeopathic formula relieves symptoms for a variety of coughs without drowsy or stimulant side effects.[3]

19. On its website Defendants make the following representations regarding its homeopathic products:

> Hyland's is celebrating over a century-long commitment to making safe and natural homeopathic medicines . . . . even during times when cultural and political factors have pushed homeopathic medicine from the mainstream, Hyland's has solidly stood its ground with integrity and wisdom, knowing that as sure as the sun rises each day, our medicines are effective, virtually free of side effects and able to be taken by nearly anyone at any time, from infants to the elderly. Today, as countless conventional medicines developed by others prove to produce complicated or even harmful side effects, the need for natural homeopathic

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10-most-dangerous-ads/ (featuring advertisements for dangerous synthetic chemicals that were once marketed as safe).

[2] Cooper, Lauren, *Sales of These Alternative Remedies are Skyrocketing. But Should You Try Them*? CONSUMER REPORTS (Nov. 30, 2015), http://www.consumerreports.org/vitamins-supplements/the-truth-about-homeopathy, (last accessed Dec. 7, 2015); *About the Natural Products Association,* NATURAL PRODUCTS ASSOCIATION (last accessed July 3, 2015), http://www.npainfo.org/NPA/About_NPA/NPA/AboutNPA/AbouttheNaturalProductsAssociation.aspx?hkey=8d3a15ab-f44f-4473-aa6e-ba27ccebcbb8.

[3] https://hylands.com/media/press-releases/hylands-inc-launches-hylands-baby-cough-syrup-infants-6-months-and-older, (last accessed Dec. 8, 2015).

> medicines that work without side effects is increasing. Hyland's stands as a leader in innovations that answer to the changing health needs of our modern world.[4]

20. Defendants represent on the packaging for each of the Products that they provide "Natural Relief" for the particular ailment(s) for which they are sold.

21. Not surprisingly, Defendants have enjoyed substantial profits from the sale of their homeopathic products. Since 2000, Hyland's has enjoyed double-digit annual growth, introduced many financially successful new products, and put its medicines on the shelves of every major drug retailer.

Defendants' Claims About the Benefits of Using the Products are False and Misleading

22. As is explained below, Defendants make numerous false and misleading representations regarding the Products.

Hyland's Baby Teething Gel

23. The packaging for Hyland's Baby Teething Gel represents prominently on the front of the product that it is "HOMEOPATHIC" and provides "Natural[,]" "FAST RELIEF OF PAIN AND IRRITABILITY FROM TEETHING." Ex. A at 1. The back of the product's packaging represents that it "Temporarily relieves symptoms of pain, simple restlessness and wakeful irritability due to cutting teeth. Helps reduce redness and inflammation of gums." Ex. A at 2.

Hyland's Baby Nighttime Tiny Cold Syrup

24. The packaging for Hyland's Baby Nighttime Tiny Cold Syrup represents prominently on the front of the product that it is "HOMEOPATHIC" and provides "Natural[,]" "RELIEF OF RUNNY NOSE, CONGESTION AND OCCASIONAL SLEEPLESSNESS DUE

[4] https://hylands.com/about, (last accessed Dec. 7, 2015), attached as Ex. C.

TO COLDS." Ex. B at 1. The back of the product's packaging represents that it "Temporarily relieves the symptoms of runny nose and eyes, cough, congestion, headache, sneezing and occasional sleeplessness due to common head colds in children." Ex. B at 2.

Hyland's Baby Cough Syrup

25. The packaging for Hyland's Baby Cough Syrup represents prominently on the front of the product that it is "HOMEOPATHIC" and provides "Natural[,]" "RELIEF OF COUGHS DUE TO COLDS." Ex. B at 3. The back of the product's packaging represents that it "Temporarily relieves the symptoms of simple, dry, tight or tickling coughs due to colds in children." Ex. B at 4.

Hyland's Baby Infant Earache Drops

26. The packaging for Hyland's Baby Infant Earache Drops represents prominently on the front of the product that it is "HOMEOPATHIC" and provides "Natural[,]" "FAST SOOTHING RELIEF OF EAR PAIN AND IRRITABILITY." Ex. B at 5. The back of the product's packaging represents that it "Temporarily relieves the symptoms of fever, pain, irritability, and sleeplessness associated with earaches in children, after diagnosis by a physician. Relieves common pain and itching of swimmer's ear." Ex. B at 6.

Hyland's Baby Gas Drops

27. The packaging for Hyland's Baby Gas Drops represents prominently on the front of the product that it is "HOMEOPATHIC" and provides "NATURAL RELIEF OF GAS DISCOMFORT AND PAIN." Ex. B at 7. The back of the product's packaging represents that it "Temporarily relieves the symptoms of gas, stomach pressure and pain, swollen tummy, restlessness, crying, burping, fussiness, groaning, gas discomfort, colic, constipation, disturbed sleep, hard tummy, and bloating." Ex. B at 8.

28. Contrary to Defendants' representations, the Products cannot provide any of these purported benefits because each of the products and homeopathic remedies are not effective.

29. Homeopathy is a 200-year old system of alternative medicine in which practitioners treat patients using highly diluted preparations that were believed to cause healthy people to exhibit symptoms that are similar to those exhibited by the patient. Homeopathy is based on two principles: "Like-Cure-Like" whereby a substance that causes a symptom to manifest in a healthy person is used in diluted form to treat the same symptom in a sick person; and "ultra-dilution" whereby the more one dilutes a substance, the more potent that substance becomes at treating the symptom ("ultra-dilution" is aided by a specific method of shaking the solutions, termed "succession" or "succession"). It is claimed that homeopathy works by stimulating the body's healing mechanisms. *See* House of Commons, Science and Technology Committee, Evidence Check 2: Homeopathy, Fourth Report, 2009-10, HC 45, 8jf 9 (U.K.).

30. The "Like-Cure-Like" principle of homeopathy, also known as the "law of similars," was first stated by German physician Samuel Hahnemann in 1796. Hahnemann believed that by using drugs to induce symptoms, the artificially induced symptoms would stimulate the "vital force," thereby neutralizing and expelling the original disease. As is explained on Hyland's website:

> Homeopathy demonstrates that a substance that produces a certain set of symptoms in a healthy person can cure a sick person experiencing those same symptoms. For instance, onions make your eyes water when you cut them. If you have a cold or allergies and your symptoms include a runny nose, the likely remedy to treat your runny nose would be Allium Cepa, which is made from onions.[5]

[5] https://hylands.com/homeopathy-and-health, (last accessed Dec. 8, 2015)

31. The settled view of medical science is that the "law of similars" is theoretically weak and "fails to provide a credible physiological mode of action for homeopathic products. *See* House of Commons, Science and Technology Committee, Evidence Check 2: Homeopathy, Fourth Report, 2009-10, HC 45, r 54 (U.K.).

32. The method homeopaths have used for over 200 years to determine which remedies were suitable for specific symptoms is called a "proving." Provings involved taking various substances and recording every twitch, sneeze, ache or itch that occurred afterward – often for several days. Followers of homeopathy took for granted that every sensation reported was caused by whatever substance was administered, and that extremely diluted doses of that same substance would then be the correct substance to treat anyone with those specific symptoms.

33. Homeopathy uses many animal, plant, mineral, chemical and poisonous substances in its remedies. Examples of substances used by homeopaths to prepare the remedies include arsenicum album (arsenic oxide), natrum muriaticum (sodium chloride or table salt), Lachesis muta (the venom of the bushmaster snake), opium and thyroidinum (thyroid hormone). Some of Hyland's homeopathic products, including its Baby Teething Gel and Baby Infant Earache Drops, list belladonna (also known as "deadly nightshade"), one of the most lethal plants in the Western Hemisphere, as an active ingredient.

34. In producing these remedies, homeopaths use a process called "dynamisation," "potentisation," or "ultra-dilution" whereby a substance is diluted with alcohol or, more commonly, distilled water. The diluting procedure specific for homeopathy is called potentisation or dynamisation. Following each dilution, homeopathic remedies are then vigorously shaken by ten hard strikes against an elastic body, in a process which homeopaths

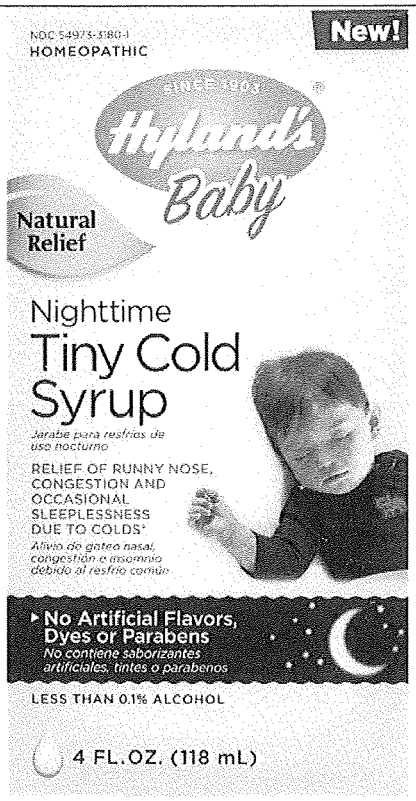
term "succession." Homeopathic products are often diluted until they contain none of the purported active ingredients at all.

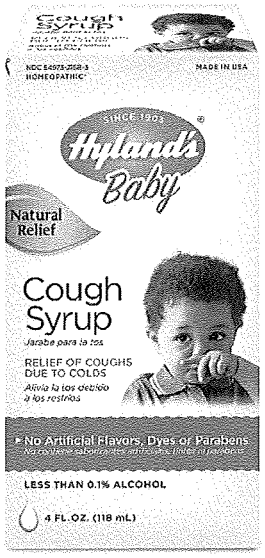
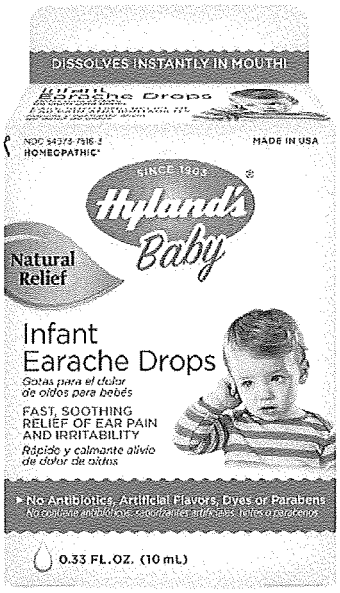
35. Homeopathic products, including those sold by Defendants, use both the decimal and centesimal scales to describe the dilution ratio of its "active ingredients." Under the decimal scale, the active substance is diluted by a factor of 10 at each stage, and is expressed as #X. Under the centesimal scale, the active substance is diluted by a factor of 100 at each stage, and is expressed as #C.

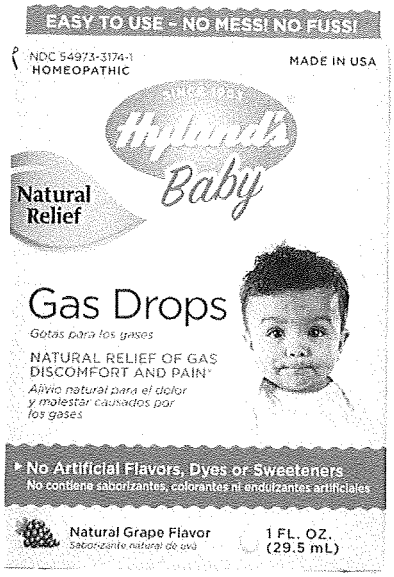
36. A representation that an ingredient is 6X means that the solution has been diluted until it contains 1 part of that ingredient per million parts of water (or 1/1,000,000). A representation that an ingredient is 12X means that the solution has been diluted until it contains 1 part of that ingredient per trillion parts of water (or 1/1,000,000,000,000). A representation that an ingredient is 30X means that the solution has been diluted until it contains 1 molecule of the ingredient per 10^{30} or $1/10^{30}$ of the solution. At a dilution of 30X, one would have to consume 8,000 gallons of the solution to consume just 1 molecule of the ingredient.[6] A representation that an ingredient is 30C means that the solution has been diluted until it contains 1 molecule of the ingredient per 100^{30} or $1/100^{30}$ of the solution. There is not enough water in the solar system to accommodate this dilution.[7]

37. The Products' purportedly active ingredients are diluted as is demonstrated in the chart below:

[6] http://www.livescience.com/31977-homeopathy.html, (last accessed Dec. 8, 2015).
[7] http://www.livescience.com/1738-homeopathy-folly-watery-memory.html, (last accessed Jan. 5, 2016).

Name of Product	Synthetic Ingredients	Photo of Product Packaging
Hyland's Baby Teething Gel	• Calcarea Phosphorica 12X • Chamomilla 6X • Coffea Cruda 6X • Belladonna 6X	
Hyland's Baby Nighttime Tiny Cold Syrup	• Chamomilla 6X • Eupatorium Perfoliatum 6X • Euphrasia Officinalis 6X • Gelsemium Sempervirens 6X • Kali Iodatum 6X.	

Hyland's Baby Cough Syrup	• Bryonia 6X, • Causticum 6X • Drosera Rotundifolia 6X • Ipecacuanha 6X • Phosphorus 12X • Rumex Crispus 6X • Spongia Tosta 6X	
Hyland's Baby Infant Earache Drops	• Belladonna 30C • Calcarea Carbonica 30C • Chamomilla 30C • Lycopodium 30C • Pulsatilla 30C • Sulphur 30C	

Hyland's Baby Gas Drops	• Argentum Nitricum 12X • Asafoetida 6X • Carbo Vegetabilis 12X • Chamomilla 6X • Cinchona Offinalis 6X • Colocynthis 6X • Lycopodium 30X • Nux Moschata 6X • Sepia 12X	

38. Thus, the Products contain no molecules of the purportedly active ingredients. To the extent that they contain any of the purportedly active ingredients, even if they were effective, they are too diluted to have any benefit.

39. According to homeopathic theory though, each dilution followed by succession is assumed to increase the effectiveness of the remedy. As is explained on Hyland's website:

> Unlike conventional medicines, a homeopathic medicine is believed to be more effective when its active ingredient is diluted and succussed (shaken vigorously). Data indicates that the homeopathic medicine gains increased effectiveness with each additional dilution-succussion step. Furthermore the safety profile of the medicine increases with increased dilution.[8]

Homeopaths call this process of ultra-dilution and succession "potentization."

40. Because they are so heavily diluted, homeopathic remedies may not contain any pharmacologically active molecules, and, therefore, for such remedies to have pharmacological effect violates fundamental principles of science. Modern homeopaths have proposed that water

[8] https://hylands.com/homeopathy-and-health, (last accessed Dec. 8, 2015)

has a memory that allows homeopathic preparations to work without any of the original substance.

41. Medical science considers the notion that ultra-dilutions can maintain an imprint of substances previously dissolved in them to be scientifically implausible. *See* House of Commons, Science and Technology Committee, Evidence Check 2: Homeopathy, Fourth Report, 2009-10, HC 45, ,r 61 (U.K.).

42. The Products are simply not effective. Moreover, expert testing has revealed that the ingredients in the products are so diluted, they simply cannot work. Additionally, the efficacy of homeopathic remedies has been rejected repeatedly by medical science. For example, in a study of homeopathic remedies commissioned by the British Government, medical scientists repeatedly expressed their criticism of homeopathy and its proponents:

> We regret that advocates of homeopathy . . . choose to rely on, and promulgate, selective approaches to the treatment of evidence base as this risks confusing or misleading the public, the media and policy makers . . . .

Id. at ¶73.

> In our view, the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos.

Id. at ¶70.

> There has been enough testing of homeopathy and plenty of evidence showing that it is not efficacious . . . .

Id. at ¶77.

> For patient choice to be real choice, patients must be adequately informed to understand the implications of treatments. For homeopathy this would certainly require an explanation that homeopathy is a placebo. When this is not done, patient choice is meaningless. When it is done, the effectiveness of the placebo – that is, homeopathy – may be diminished.

Id. at ¶70.

43. After its investigation, the British Government found that:

> [T]he evidence base shows that homeopathy is not efficacious (that is, it does not work beyond the placebo effect) and that explanations for why homeopathy would work are scientifically implausible . . . . The [Science and Technology] Committee concluded, given that the existing scientific literature showed no good evidence of efficacy, that further clinical trials of homeopathy could not be justified . . . . In the Committee's view, homeopathy is a placebo treatment and the Government should have a policy on prescribing placebos. Prescribing of placebos is not consistent with informed patient choice, which the Government claims is very important, as it means patients do not have all the information needed to make choice meaningful . . . . Beyond ethical issues and the integrity of the doctor-patient relationship, prescribing pure placebos is bad medicine. Their effect is unreliable and unpredictable and cannot form the basis of any treatment on the NHS.

See Press Release, Science and Technology Committee, MPS Urge Government to Withdraw NHS Funding and MHRA Licensing of Homeopathy (February 22, 2010), available at http://www.parliament.uk/business/committees/committees-archive/science-technology/s-t-homeopathy-inquiry/.

44. Michael Levy, director of the Food and Drug Administration's ("FDA") division of new drugs and labeling compliance, has stated that the FDA is "not aware of any evidence that shows homeopathic drugs are effective." Indeed, the American medical establishment has long rejected the science underlying homeopathic studies, saying the compounds are too diluted to have any meaningful or measurable medicinal value. "Science tells us that most of these medicines aren't useful," said Dr. Wayne Yankus, a Midland Park pediatrician, discussing the efficacy of homeopathic remedies. *See* Colleen Diskin, *Parents Look to Homeopathy as Alternative to Over-The-Counter Cold Medicines*, THE RECORD (Dec. 19, 2010).[9]

45. In 2005, a meta-analysis of 110 placebo controlled trials of the efficacy of homeopathy was published in The Lancet. It concluded that the results of high quality trials of

[9] http://www.northjersey.com/news/over-the-counter-alternatives-1.201021?page=all, (last accessed Dec. 6, 2015).

homeopathy were consistent with the conclusion that the clinical effects of homeopathy are a placebo effect. *See* Aijing Shang, MD, et al., *Are the Clinical Effects of Homeopathy Placebo Effects? Comparative Study of Placebo-Controlled Trials of Homeopathy and Allopathy*, LANCET Vol. 366, No. 9487, p. 726-32 (Aug. 27, 2005).

46. The Cochrane Collaboration is regarded as the single best source of information on the safety and efficacy of health interventions. Meta-analyses conducted by the Cochrane Collaboration on the efficacy of homeopathic remedies have similarly concluded that they perform no better than a placebo. For example, a meta-analysis of trials of homeopathic remedies for the treatment of attention deficit and hyperactivity disorder ("ADHD") found that homeopathic remedies did not have an effect on ADHD. Morag Heirs, Mike Emmans Dean, *Homeopathy for Attention Deficit/Hyperactivity Disorder or Hyperkinetic Disorder*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS (Oct. 17, 2007). A review of homeopathy for the induction of labor found that it was no more effective than a placebo. Caroline A. Smith, *Homeopathy for Induction of Labour*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS (Oct. 20, 2003).

47. Indeed, even the initial study conducted by Samuel Hahnemann that supposedly established the benefits of homeopathy, when replicated, has shown that homeopathy is nothing more than a placebo. *See* Simon Singh, Edzard Ernst, MD, TRICK OR TREATMENT, THE UNDENIABLE FACTS ABOUT ALTERNATIVE MEDICINE 141 (1st ed. 2008).

48. Thus, Defendants make their claims about the benefits of consuming the Products (i.e. "safe and effective"), despite the Products being ineffective.

The FDA Does Not Regulate Homeopathic Remedies, Further Necessitating the Need for Judicial Intervention

49. Congress enacted the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq*. in 1938 after Congress "became increasingly concerned about unsafe drugs and fraudulent marketing." *Wyeth v. Levine*, 129 S.Ct. 1187, 1198-99 (2009). Among other things, the FDCA prohibits the sale of adulterated or misbranded drugs, and requires manufacturers to apply to the FDA for premarket approval of new drugs. *See* 21 U.S.C. § 331.

50. The FDCA defines "drug" to include articles like the Products that are recognized in the official Homeopathic Pharmacopoeia of the United States ("HPUS") and includes both prescription and OTC drugs. *See* 21 U.S.C. § 321(g)(1). Homeopathic OTC drugs, however, are treated as a subset of OTC drugs by the FDCA and its various regulations, and are not subject to the same evaluation, testing and substantiation requirements that the FDA applies to conventional non-homeopathic OTC drugs.

51. The FDA subjects non-homeopathic OTC drugs to stringent evaluations and testing to determine whether such drugs are safe, effective and not misbranded using a drug monograph system created by the FDA. *See* 21 C.F.R. §§ 330.1, 330.10. In drafting the monographs, the FDA divided the non-homeopathic OTC drugs into drug categories, which were then assigned an advisory review panel of qualified experts who evaluate the safety and effectiveness of the non-homeopathic OTC drugs, as well as reviewing the drugs' labeling, and advising the FDA Commissioner on the promulgation of monographs establishing conditions under which non-homeopathic OTC drugs listed within each monograph are generally recognized as safe, effective, and not misbranded. *See* 21 C.F.R. § 330.10(a).

52. Under this system, a manufacturer seeking approval of a new non-homeopathic OTC drug must subject a detailed new drug application, which must include:

> [E]vidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

See 21 U.S.C. § 355. Moreover, after the FDA approves a new drug application, any change in the drug's labeling requires a supplement to the application, and further approval by the FDA, either before or after the change. *See* 21 C.F.R. §§ 314.70(b),(c), 314.71.

53. In stark contrast, unlike non-homeopathic OTC drugs, homeopathic OTC drugs, including the Products, are not approved or authorized by the FDA at all. Indeed, the FDA has acknowledged that many homeopathic drugs are manufactured and distributed without FDA approval or authorization under its enforcement policies.

54. The FDA defines a homeopathic drug as any drug labeled as being homeopathic that is also listed in the HPUS, an addendum, or its supplements. *See* 21 U.S.C. § 321(g)(1)(A); FDA, Inspections, Compliance, Enforcement, and Criminal Investigations, Compliance Policy Guides § 400.400, "Conditions Under Which Homeopathic Drugs May be Marketed" ("CPG § 400.400").[10]

55. According to the FDA, the HPUS is "[a] compilation of standards for source, composition, and preparation of homeopathic drugs. The HPUS contains monographs of drug ingredients used in homeopathic treatment." CPG § 400.400. Although the HPUS describes how these ingredients are prepared for homeopathic use, it does not list the drugs as fit to treat

[10] http://www.gmp-compliance.org/guidemgr/files/CPG%20HOMEOPATHIC%20DRUGS.PDF.

specific symptoms, ailments, or conditions. Instead, the HPUS allow the practitioner or manufacturer to set forth the substance's indications for use.

56. Thus, rather than the stringent testing and evaluation applied to other OTC drugs, homeopathic OTC drug substances are included in the HPUS after having been subjected to the "provings" described above, which were conducted in the 1800s and early 1900s to establish what types of symptoms resulted from the use of a homeopathic substance in a healthy person.

57. The FDA does not impose additional standards for strength, purity, quality, safety, or efficacy on homeopathic OTC remedies. Indeed, the FDA has advised that unless a homeopathic remedy is "being offered for use (or promoted) significantly beyond recognized or customary practice of homeopathy," federal policies on health fraud to not apply. FDA's Compliance Policy Guide § 400.400 (the "CPG").

58. The FDA requires that the labels on homeopathic remedies include at least one major indication (*i.e.*, medical problem to be treated), a list of ingredients, the dilution, and safety instructions. Notably, however, pursuant to FDA Compliance Guidelines, compliance with this labeling requirement or a "product's compliance with requirements of the HPUS . . . ***does not show that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use."*** *Id.* (emphasis added).

59. The CPG further provides that only "[h]omeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed OTC. ***Homeopathic products offered for conditions not amenable to OTC use must be marketed.***" *Id.* (emphasis added).

The Products are Misbranded

60. The FDCA prohibits the sale of misbranded drugs, whether they are conventional or homeopathic. *See, e.g.*, 21 U.S.C. § 331. Under the FDCA, a drug will be deemed to be misbranded if the label is false or misleading. *See* 21 U.S.C. § 352(a). The term "labeling" is defined to include "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *See* 21 U.S.C. § 321(m).

61. As is explained above in paragraphs [2, 3, 17, 18, 19, 28, 38, 39, 42, 44, 46, 48, 51, 52 & 58], given that the Products are not effective, Defendants' representations about the Products are false and misleading. Thus, they are misbranded under 21 U.S.C. § 352(a).

Defendants' Claims That the Products are Natural are False and Misleading

62. In addition to misrepresenting the benefits represented on the Products' packaging, the Products also are not natural because they contain artificial and synthetic ingredients, some of which have been associated with the development of severe health problems.

63. United States regulatory organizations have clearly delineated between natural ingredients and synthetic ingredients.

64. In 2013, the USDA issued a Draft Guidance Decision Tree for Classification of Materials as Synthetic or Nonsynthetic (Natural). In accordance with this decision tree, a substance is natural—as opposed to synthetic—if: (a) it is manufactured, produced, or extracted from a natural source (i.e. naturally occurring mineral or biological matter); (b) it has not undergone a chemical change (i.e. a process whereby a substance is transformed into one or more other distinct substances) so that it is chemically or structurally different than how it naturally occurs in the source material; or (c) the chemical change was created by a naturally

occurring biological process such as composting, fermentation, or enzymatic digestion or by heating or burning biological matter. Ex. D.

65. The term "synthetic" is also defined by federal statute as "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes." 7 U.S.C. § 6502(21).

66. In addition, Webster's New World Dictionary defines natural as "produced or existing in nature, not artificial or manufactured."[11]

67. Each of the Products contains synthetic ingredients, including ingredients that are associated with the development of severe health problems. The Products contain synthetic ingredients as follows: Hyland's Baby Teething Gel contains Calcarea Phosphorica, Hydroxyethylcellulose, Sodium Benzoate, Potassium Sorbate, Sorbic Acid, and Vegetable Glycerin; Hyland's Baby Nighttime Tiny Cold Syrup contains Sodium Benzoate and Vegetable Glycerin; Hyland's Baby Cough Syrup contains Sodium Benzoate and Vegetable Glycerin; Hyland's Baby Infant Earache Drops contains Sodium Benzoate and Vegetable Glycerin; and Hyland's Baby Gas Drops contains Sodium Benzoate and Vegetable Glycerin. As is explained below, each of these ingredients is artificial and synthetic:

a. **Sodium benzoate** is a chemical preservative.[12] Sodium benzoate is produced by the neutralization of benzoic acid with sodium hydroxide, or by adding benzoic acid to a hot concentrated solution of sodium carbonate until effervescence

[11] http://www.yourdictionary.com/natural#websters (last visited Oct. 11, 2015).
[12] http://www.ewg.org/skindeep/ingredient/705989/SODIUM_BENZOATE/; http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm274535.htm.

ceases. The solution is then evaporated, cooled and allowed to crystalize or evaporate to dryness, and then granulated. It does not occur naturally.[13] Sodium benzoate has been shown to cause DNA damage and chromosomal aberrations.[14] When sodium benzoate combines with ascorbic acid (an ingredient common in many food products) the two substances can react to produce benzene, which is a highly toxic carcinogen.

b. **Potassium Sorbate** is a chemical preservative.[15] *See* 21 C.F.R. § 582.3640. It is created by using potassium hydroxide (KOH) to neutralize sorbic acid (C6H8O2). Studies have shown Potassium Sorbate to have genotoxic effects on humans and other mammals.[16] It causes chromosomal aberrations in cells, which can trigger the development of cancer.[17]

c. **Calcarea Phosphorica** (10CaO·3P2O5·H2O) is a white, amorphous, tasteless, odorless powder. It is extracted from bones by dissolving them in hydrochloric acid and precipitating with ammonium hydroxide. *See* Ex. E.

d. **Vegetable Glycerin** is a well-recognized synthetic product. *See* 21 C.F.R. § 172.866; 7 C.F.R. § 205.605(b); 7 C.F.R. § 205.603; 21 C.F.R. § 178.3500. The Plaintiff believes, and therefore avers, that the vegetable glycerin used in the Product is synthesized using one or both commonly used manufactured methods – hydrolysis of fats and oils or hydrogenolysis of carbohydrates or propylene – and

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[13] 21 C.F.R. § 184.1733.
[14] N. Zengin et al., *The Evaluation of the Genotoxicity of Two Food Preservatives: Sodium Benzoate and Potassium Benzoate*, FOOD AND CHEMICAL TOXICOLOGY 763, 764-68 (2011).
[15] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm274535.htm.
[16] Sevcan Mamur et al., *Does Potassium Sorbate Induce Genotoxic or Mutagenic Effects in Lymphocytes?*, TOXICOLOGY IN VITRO 790, 793 (2010).
[17] *Id.*

not derived naturally. Glycerin (a/k/a Glycerine, Glycerol or Vegetable Glycerin) is a synthetic alcohol that rarely exists in its free form in nature. Glycerin is commonly manufactured for commercial use through (1) hydrolysis of fats and oils, or (2) synthesized from the hydrogenolysis of carbohydrates or petrochemicals. A technical evaluation report compiled by the USDA AMS Agricultural Analytics Division for the USDA National Organic Program explains that Glycerin is "produced by a hydrolysis of fats and oils" and is listed in the USDA Organic Program's National List as a "synthetic nonagricultural (nonorganic) substance." The same report lists several methods of producing Glycerin, each of which involve numerous steps that include the use of high temperatures and pressure and purification to get an end product:

Table 2 Processes for producing glycerin by hydrolysis of fats and oils	
Lemmens Fryer's Process	Oil or fat is subjected in an autoclave to the conjoint action of heat and pressure (about 100 PSI) in the presence of an emulsifying and accelerating agent, e.g. zinc oxide or hydroxide (sodium hydroxide can be substituted) for about eight hours. The strong solution of glycerin formed is withdrawn and replaced by a quantity of hot, clean and preferably distilled water equal to about one third to one fourth of the weight of the original charge of oil or fat and treatment continued for an additional four hours. The dilute glycerin obtained from the latter part of the process is drawn off and used for the initial treatment of the further charge of oil or fat.
Budde and Robertson's Process	The oils or fats are heated and mechanically agitated with water and sulphuric acid gas, under pressure in a closed vessel or autoclave. The advantage claimed for the process are that the contents of the vessel are free from foreign matter introduced by reagents and need no purification; that the liberated glycerin is in the form of a pure and concentrated solution; that no permanent emulsion is formed and that the fatty acids are not discolored.
Ittner's Process	Coconut oil is kept in an autoclave in the presence of water at 70 atmospheres pressure and 225-245°C temperature and split into fatty acids and glycerin, both being soluble under these conditions in water. The glycerin solution separates in the bottom of the autoclave. The aqueous solution contains at the end of the splitting process more than 30 percent glycerin.

Continuous High Pressure Hydrolysis	In this process a constant flow of fat is maintained flowing upward through an autoclave column tower against a downward counter-flow of water at a pressure of 600 PSI maintained at temperature of 480-495°F. Under these conditions, the fat is almost completely miscible in water and the hydrolysis take place in a very short time. The liberated fatty acids, washed free of glycerin by the downward percolating water, leave the top of the column and pass through a flash tank while the liberated glycerin dissolves in the downward flow of water and is discharged from the bottom of the tower into the sweet-water storage tank.

e. **Hydroxyethylcellulose** is a modified cellulose polymer. It is used as a gelling and thickening agent.

f. **Sorbic Acid** is a chemical preservative. *See* 21 C.F.R. § 582.3089. It is produced commercially by condensing crotonaldehyde and ketene in the presence of boron trifluoride.

68. Given the presence of these synthetic and artificial ingredients in the Products, Defendants' representations that they are natural are deceptive and misleading.

69. A reasonable consumer's understanding of the term "natural" comports with that of federal regulators and common meaning. That is, the reasonable consumer understands the term "natural" to mean that none of the ingredients are synthetic or artificial.

70. Furthermore, consumers lack the meaningful ability to test or independently ascertain or verify whether a product is natural, especially at the point of sale. Consumers would not know the true nature of the ingredients merely by reading the ingredients label.

71. Discovering that the ingredients are unnatural and synthetic requires a scientific investigation and knowledge of chemistry beyond that of the average consumer. That is why, even though Calcarea Phosphorica, Sodium Benzoate, Vegetable Glycerin, Potassium Sorbate Hydroxyethylcellulose, and Sorbic Acid are listed in the ingredients lists on the back of the Products' packaging, the reasonable consumer would not understand – nor is she expected to understand - that these ingredients are synthetic.

72. Moreover, the reasonable consumer is not expected or required to scour the ingredients list on the back of a product in order to confirm or debunk claims, representations and warranties prominently made on the front of a product's packaging.

73. Defendants did not disclose that Calcarea Phosphorica, Sodium Benzoate, Vegetable Glycerin, Hydroxyethylcellulose, Potassium Sorbate, and Sorbic Acid are synthetic ingredients. A reasonable consumer understands Defendants' natural claim to mean that the Products are natural and do not contain synthetic ingredients.

74. Defendants' material misrepresentation that the Products are homeopathic, and provide "natural relief" for the ailments and symptoms thereof for which they are marketed and sold induced Plaintiffs and Class Members to purchase the Products at a premium price. Plaintiffs and Class Members relied on Defendants' false and misleading misrepresentations. If not for Defendants' misrepresentations, Plaintiffs and Class Members would not have been willing to purchase the Products at a premium price. Accordingly, they have suffered an injury as a result of Defendants' misrepresentations.

CLASS ALLEGATIONS

75. Plaintiffs bring this matter on behalf of themselves and those similarly situated. As detailed at length in this Complaint, Defendants orchestrated deceptive marketing and labeling practices. Defendants' customers were uniformly impacted by and exposed to this misconduct. Accordingly, this Complaint is uniquely situated for class-wide resolution, including injunctive relief.

76. The Class is defined as all consumers who purchased the Products anywhere in the United States during the Class Period (the "Class").

77. Plaintiffs also seeks certification, to the extent necessary or appropriate, of a subclass of individuals who purchased the product in the State of New York at any time during the Class Period (the "New York Subclass").

78. The Class and New York Subclass shall be referred to collectively throughout the Complaint as the Class.

79. The Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

80. Numerosity: Class Members are so numerous that joinder of all members is impracticable. Plaintiffs believe that there are thousands of consumers who are Class Members described above who have been damaged by Defendants' deceptive and misleading practices.

81. Commonality: The questions of law and fact common to the Class Members which predominate over any questions which may affect individual Class Members include, but are not limited to:

a. Whether Defendants are responsible for the conduct alleged herein which was uniformly directed at all consumers who purchased the Products;

b. Whether Defendants' misconduct set forth in this Complaint demonstrates that Defendants have engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sale of the Products;

c. Whether Defendants made false and/or misleading statements to the Class and the public concerning the content and safety of the Products.

d. Whether Defendants' false and misleading statements concerning the Products were likely to deceive the public;

e. Whether Plaintiffs and the Class are entitled to injunctive relief;

f. Whether Plaintiffs and the Class are entitled to money damages under the same causes of action as the other Class Members.

82. Typicality: Plaintiffs are a member of the Class. Plaintiffs' claims are typical of the claims of each Class Member in that every member of the Class was susceptible to the same deceptive, misleading conduct and purchased the Defendants' Products. Plaintiffs are entitled to relief under the same causes of action as the other Class Members.

83. Adequacy: Plaintiffs are an adequate Class representative because their interests do not conflict with the interests of the Class Members they seek to represent; their consumer fraud claims are common to all members of the Class and they has a strong interest in vindicating their rights; they have retained counsel competent and experienced in complex class action litigation and they intend to vigorously prosecute this action. Plaintiffs have no interests which conflict with those of the Class. The Class Members' interests will be fairly and adequately protected by Plaintiffs and their counsel. Defendants have acted in a manner generally applicable to the Class, making relief appropriate with respect to Plaintiffs and the Class Members. The prosecution of separate actions by individual Class Members would create a risk of inconsistent and varying adjudications.

84. The Class is properly brought and should be maintained as a class action under Rule 23(b) because a class action is superior to traditional litigation of this controversy. Pursuant to Rule 23(b)(3), common issues of law and fact predominate over any other questions affecting only individual members of the Class. The Class issues fully predominate over any individual issue because no inquiry into individual conduct is necessary; all that is required is a narrow focus on Defendants' deceptive and misleading marketing and labeling practices. In addition,

this Class is superior to other methods for fair and efficient adjudication of this controversy because, *inter alia*:

85. Superiority: A class action is superior to the other available methods for the fair and efficient adjudication of this controversy because:

a. The joinder of thousands of individual Class Members is impracticable, cumbersome, unduly burdensome, and a waste of judicial and/or litigation resources;

b. The individual claims of the Class Members may be relatively modest compared with the expense of litigating the claim, thereby making it impracticable, unduly burdensome, and expensive—if not totally impossible—to justify individual actions;

c. When Defendants' liability has been adjudicated, all Class Members' claims can be determined by the Court and administered efficiently in a manner far less burdensome and expensive than if it were attempted through filing, discovery, and trial of all individual cases;

d. This class action will promote orderly, efficient, expeditious, and appropriate adjudication and administration of Class claims;

e. Plaintiffs know of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action;

f. This class action will assure uniformity of decisions among Class Members;

g. The Class is readily definable and prosecution of this action as a class action will eliminate the possibility of repetitious litigation;

h. Class Members' interests in individually controlling the prosecution of separate actions is outweighed by their interest in efficient resolution by single class action; and

i. It would be desirable to concentrate in this single venue the litigation of all plaintiffs who were induced by Defendants' uniform false advertising to purchase the Products.

86. Accordingly, this Class is properly brought and should be maintained as a class action under Rule 23(b)(3) because questions of law or fact common to Class Members predominate over any questions affecting only individual members, and because a class action is superior to other available methods for fairly and efficiently adjudicating this controversy.

INJUNCTIVE CLASS RELIEF

87. Rules 23(b)(1) and (2) contemplate a class action for purposes of seeking class-wide injunctive relief. Here, Defendants have engaged in conduct resulting in misleading consumers about ingredients and the benefits of the subject Products. Since Defendants' conduct has been uniformly directed at all consumers in the United States, and the conduct continues presently, injunctive relief on a class-wide basis is a viable and suitable solution to remedy Defendants' continuing misconduct.

88. The injunctive Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

a. Numerosity: Individual joinder of the injunctive Class Members would be wholly impracticable. Defendants' Products have been purchased by thousands of people throughout the United States.

b. Commonality: Questions of law and fact are common to members of the Class. Defendants' misconduct was uniformly directed at all consumers. Thus, all members of the Class have a common cause against Defendants to stop their misleading conduct through an injunction. Since the issues presented by this injunctive Class deal exclusively with Defendants' misconduct, resolution of these questions would necessarily be common to the entire Class. Moreover, there are common questions of law and fact inherent in the resolution of the proposed injunctive class, including, *inter alia*:

i. Resolution of the issues presented in the 23(b)(3) class;

ii. Whether members of the Class will continue to suffer harm by virtue of Defendants' deceptive product marketing and labeling; and

iii. Whether, on equitable grounds, Defendants should be prevented from continuing to deceptively mislabel the Products as providing "natural relief" for the above mentioned ailments and the symptoms thereof for which each of the Products is marketed and sold.

c. Typicality: Plaintiffs' claims are typical of the claims of the injunctive Class because their claims arise from the same course of conduct (i.e. Defendants' deceptive and misleading marketing, labeling, and advertising practices). Plaintiffs are typical representatives of the Class because, like all members of the injunctive Class, they purchased Defendants' Products which were sold unfairly and deceptively to consumers throughout the United States.

d. Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of the injunctive Class. Their consumer protection claims are common to all

members of the injunctive Class and they have a strong interest in vindicating their rights. In addition, Plaintiffs and the Class are represented by counsel who is competent and experienced in both consumer protection and class action litigation.

89. The injunctive Class is properly brought and should be maintained as a class action under Rule 23(b)(2) because Plaintiffs seek injunctive relief on behalf of the Class Members on grounds generally applicable to the entire injunctive Class. Certification under Rule 23(b)(2) is appropriate because Defendants has acted or refused to act in a manner that applies generally to the injunctive Class (i.e. Defendants has marketed its Products using the same misleading and deceptive labeling to all of the Class Members). Any final injunctive relief or declaratory relief would benefit the entire injunctive Class as Defendants would be prevented from continuing its misleading and deceptive marketing practices and would be required to honestly disclose to consumers the nature of the contents of its Products.

FIRST CAUSE OF ACTION
VIOLATION OF NEW YORK GBL § 349
(On Behalf of Plaintiffs and All Class and/or New York Subclass Members)

90. Plaintiffs repeat and reallege each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

91. New York General Business Law Section 349 ("GBL § 349") declares unlawful "[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state . . ."

92. The conduct of Defendants alleged herein constitutes recurring, "unlawful" deceptive acts and practices in violation of GBL § 349, and as such, Plaintiffs and the Class and/or New York Subclass Members seek monetary damages and the entry of preliminary and

permanent injunctive relief against Defendants, enjoining it from inaccurately describing, labeling, marketing, and promoting its Products.

93. There is no adequate remedy at law.

94. Defendants misleadingly, inaccurately, and deceptively presents its Products to consumers.

95. Defendants' improper consumer-oriented conduct—including labeling and advertising the Products as providing "natural relief" for the ailments for which they are marketed and sold—is misleading in a material way in that it, *inter alia*, induced Plaintiffs and Class and/or New York Subclass Members to purchase and pay a premium for Defendants' Products and to use these Products when they otherwise would not have.

96. Defendants made their untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

97. Plaintiffs and the Class and/or New York Subclass Members have been injured inasmuch as they paid a premium for products that were—contrary to Defendants' representations—unable to relieve any of the ailments or symptoms for which they were marketed and sold, and were not natural. Accordingly, Plaintiffs and the Class and/or New York Subclass Members received less than what they bargained and/or paid for.

98. Defendants' advertising and Products' packaging and labeling induced the Plaintiffs and Class and/or New York Subclass Members to buy Defendants' Products and to pay a premium price for them.

99. Defendants' deceptive and misleading practices constitute a deceptive act and practice in the conduct of business in violation of New York General Business Law §349(a) and Plaintiffs and the Class have been damaged thereby.

100. As a result of Defendants' recurring, "unlawful" deceptive acts and practices, Plaintiffs and Class and/or New York Subclass Members are entitled to monetary, compensatory, treble and punitive damages, injunctive relief, restitution and disgorgement of all moneys obtained by means of Defendants' unlawful conduct, interest, and attorneys' fees and costs.

SECOND CAUSE OF ACTION
VIOLATION OF NEW YORK GBL § 350
(On Behalf of Plaintiffs and All Class and/or New York Subclass Members)

101. Plaintiffs repeat and reallege each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

102. N.Y. Gen. Bus. Law § 350 provides, in part, as follows:

> False advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful.

103. N.Y. Gen. Bus. Law § 350a(1) provides, in part, as follows:

> The term 'false advertising, including labeling, of a commodity, or of the kind, character, terms or conditions of any employment opportunity if such advertising is misleading in a material respect. In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity or employment to which the advertising relates under the conditions proscribed in

> said advertisement, or under such conditions as are customary or usual . . .

104. Defendants' labeling and advertisements contain untrue and materially misleading statements concerning Defendants' Products inasmuch as they misrepresent that the Products provide "natural relief" for the ailments for which they are marketed and sold

105. Plaintiffs and the Class and/or New York Subclass Members have been injured inasmuch as they relied upon the labeling, packaging and advertising and paid a premium for Products that—contrary to Defendants' representations—do not provide relief for the ailments for which they are marketed and sold and are not natural. Accordingly, Plaintiffs and the Class and/or New York Subclass Members received less than what they bargained and/or paid for.

106. Defendants' advertising, packaging and product labeling induced the Plaintiffs and Class and/or New York Subclass Members to buy Defendants' Products.

107. Defendants made their untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

108. Defendants' conduct constitutes multiple, separate violations of N.Y. Gen. Bus. Law § 350.

109. Defendants made the material misrepresentations described in this Complaint in Defendants' advertising, and on the Products' packaging and labeling.

110. Defendants' material misrepresentation were substantially uniform in content, presentation, and impact upon consumers at large. Moreover, all consumers purchasing the Products were and continue to be exposed to Defendants' material misrepresentations.

111. As a result of Defendants' recurring, "unlawful" deceptive acts and practices, Plaintiffs and Class and/or New York Subclass Members are entitled to monetary, compensatory,

treble and punitive damages, injunctive relief, restitution and disgorgement of all moneys obtained by means of Defendants' unlawful conduct, interest, and attorneys' fees and costs.

THIRD CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION STATUTES
(On Behalf of Plaintiffs and All Class Members)

112. Plaintiffs repeat and reallege each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

113. Plaintiffs and Class Members have been injured as a result of Defendants' violations of the following state consumer protection statutes, which also provide a basis for redress to Plaintiffs and unnamed Calls Members/representatives based on Defendants' fraudulent, deceptive, unfair and unconscionable acts, practices and conduct.

114. Defendants' conduct as alleged herein violates the consumer protection, unfair trade practices and deceptive acts laws of each of the following jurisdictions:

a. **Alaska:** Defendants' practices were and are in violation of Alaska's Unfair Trade Practices and Consumer Protection Act, Alaska Stat. § 45.50.471, *et seq.*

b. **Arizona:** Defendants' practices were and are in violation of Arizona's Consumer Fraud Act, Ariz. Rev. Stat. Ann. §§ 44-1521, *et seq.*

c. **Arkansas:** Defendants' practices were and are in violation of Arkansas Code Ann. § 4-88-101, *et seq.*

d. **California:** Defendants' practices were and are in violation of California Consumer Legal Remedies Act, Civil Code § 1750, *et seq.*, and California's Unfair Competition Law, California Business and Professions Code § 17200, *et seq.*

e. **Colorado**: Defendants' practices were and are in violation of Colorado's Consumer Protection Act, Colo. Rev. Stat. §§ 61-1-101, *et seq.*

f. **Connecticut:** Defendants' practices were and are in violation of Connecticut's Gen. Stat. § 42-110a, *et seq.*

g. **Delaware:** Defendants' practices were and are in violation of Delaware's Consumer Fraud Act, Del. Code Ann. tit. 6, § 2511, *et seq.* and the Deceptive Trade Practices Act, Del. Code Ann. tit. 6, § 2531, *et seq.*

h. **District of Columbia:** Defendants' practices were and are in violation of the District of Columbia's Consumer Protection Act, D.C. Code § 28-3901, *et seq.*

i. **Florida:** Defendants' practices were and are in violation of the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, *et seq*.

j. **Hawaii:** Defendants' practices were and are in violation of the Hawaii's Uniform Deceptive Trade Practices Act, Haw. Rev. Stat. § 481A-1, *et seq.* and Haw. Rev. Stat. § 480-2.

k. **Idaho:** Defendants' practices were and are in violation of Idaho's Consumer Protection Act, Idaho Code Ann. § 48-601, *et seq.*

l. **Illinois:** Defendants' acts and practices were and are in violation of Illinois' Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/2; and Uniform Deceptive Trade Practices Act, 815 Ill. Comp. Stat. 510/2.

m. **Indiana:** Defendants' practices were and are in violation of Indiana's Deceptive Consumer Sales Act, Ind. Code Ann. § 24-5-0.5-1, *et seq.*

n. **Kansas:** Defendants' practices were and are in violation of Kansas's Consumer Protection Act, Kat. Stat. Ann. § 50-623, *et seq*.

o. **Kentucky:** Defendants' practices were and are in violation of Kentucky's Consumer Protection Act, Ky. Rev. Stat. Ann. § 367.110, *et seq.*

p. **Maine:** Defendants' practices were and are in violation of the Maine Unfair Trade Practices Act, 5 Me. Rev. Stat. Ann. Tit. 5, § 205-A, *et seq*. and 10 Me. Rev. Stat. Ann. § 1101, *et seq*.

q. **Maryland:** Defendants' practices were and are in violation of Maryland's Consumer Protection Act, Md. Code Ann. Com. Law § 13-101, *et seq*.

r. **Massachusetts:** Defendants' practices were unfair and deceptive acts and practices in violation of Massachusetts' Consumer Protection Act, Mass. Gen. Laws ch. 93A, § 2.

s. **Michigan:** Defendants' practices were and are in violation of Michigan's Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901, *et seq*.

t. **Minnesota:** Defendants' practices were and are in violation of Minnesota's Prevention of Consumer Fraud Act, Minn. Stat. § 325F.68, *et seq.* and the Unlawful Trade Practices law, Minn. Stat. § 325D.09, *et seq.*

u. **Missouri:** Defendants' practices were and are in violation of Missouri's Merchandising Practices Act, Mo. Rev. Stat. § 407.010, *et seq.*

v. **Nebraska:** Defendants' practices were and are in violation of Nebraska's Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.* and the Uniform Deceptive Trade

Practices Act, § 87-302, *et seq.*

w. **Nevada:** Defendants' practices were and are in violation of Nevada's Deceptive Trade Practices Act, Nev. Rev. Stat. Ann. §§ 598.0903 and 41.600.

x. **New Hampshire:** Defendants' practices were and are in violation of New Hampshire's Regulation of Business Practices for Consumer Protection, N.H. Rev. Stat. Ann. § 358-A:1, *et seq*.

y. **New Jersey:** Defendants' practices were and are in violation of New Jersey's Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1, *et seq*.

z. **New Mexico:** Defendants' practices were and are in violation of New Mexico's Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, *et seq.*

aa. **New York:** Defendants' practices were in and are in violation of New York's Gen. Bus. Law §§ 349, *et seq*.

bb. **North Carolina:** Defendants' practices were and are in violation of North Carolina's Unfair Deceptive Trade Practices Act, N.C. Gen. Stat. Ann. § 75-1, *et seq*.

cc. **North Dakota:** Defendants' practices were and are in violation of North Dakota's Unlawful Sales or Advertising Practices law, N.D. Cent. Code § 51-15-01, *et seq.*

dd. **Ohio:** Defendants' practices were and are in violation of Ohio's Consumer Sales Practices Act, Ohio Rev. Code Ann. § 1345.01, *et seq*. and Ohio's Deceptive Trade Practices Act. Ohio Rev. Code Ann. § 4165.01, *et seq*.

ee. **Oklahoma:** Defendants' practices were and are in violation of Oklahoma's Consumer Protection Act, Okla. Stat. Ann. tit. 15 § 751, *et seq.*, and Oklahoma's Deceptive Trade Practices Act, Okla. Stat. Ann. tit. 78 § 51, *et seq.*

ff. **Oregon:** Defendants' practices were and are in violation of Oregon's Unlawful Trade Practices law, Or. Rev. Stat. § 646.605, *et seq.*

gg. **Pennsylvania:** Defendants' practices were and are in violation of Pennsylvania's Unfair Trade Practice and Consumer Protection Law, 73 Pa. Stat. Ann. § 201-1, *et seq*.

hh. **Rhode Island:** Defendants' practices were and are in violation of Rhode Island's Deceptive Trade Practices Act, R.I. Gen. Laws § 6-13.1-1, *et seq.*

ii. **South Dakota:** Defendants' practices were and are in violation of South Dakota's Deceptive Trade Practices and Consumer Protection Act, S.D. Codified Laws § 37-24-1, *et seq.*

jj. **Texas:** Defendants' practices were and are in violation of Texas' Deceptive Trade Practices Consumer Protection Act, Tex. Bus. & Com. Code Ann. § 17.41, *et seq.*

kk. **Utah:** Defendants' practices were and are in violation of Utah's Consumer Sales Practices Act, Utah Code Ann. § 13-11-1, *et seq.*, and Utah's Truth in Advertising Law, Utah Code Ann. § 13-11a-1, *et seq.*

ll. **Vermont:** Defendants' practices were and are in violation of Vermont's Consumer Fraud Act, Vt. Stat. Ann. tit. 9 § 2451, *et seq.*

mm. **Washington:** Defendants' practices were and are in violation of Washington Consumer Protection Act, Wash. Rev. Code Ann. § 19.86, *et seq*.

nn. **West Virginia:** Defendants' practices were and are in violation of West Virginia's Consumer Credit and Protection Act, W. Va. Code § 46A-6-101, *et seq.*

oo. **Wisconsin:** Defendants' practices were and are in violation of Wisconsin's Consumer Act, Wis. Stat. §421.101, *et seq*.

pp. **Wyoming:** Defendants' practices were and are in violation of Wyoming's Consumer Protection Act, Wyo. Stat. Ann. §40-12-101, *et seq*.

115. Defendants violated the aforementioned states' unfair and deceptive acts and practices laws by representing that the Products provide "natural relief" for the ailments for which they are marketed and sold.

116. Contrary to Defendants' representations, the Products do not provide relief for the ailments for which they are marketed and sold and are not natural.

117. Defendants' misrepresentations were material to Plaintiffs' and Class Members' decision to pay a premium for the Products.

118. Defendants made their untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

119. As a result of Defendants' violations of the aforementioned states' unfair and deceptive practices laws, Plaintiffs and Class Members paid a premium for the Products.

120. As a result of Defendants' violations, Defendants have been unjustly enriched.

121. Pursuant to the aforementioned states' unfair and deceptive practices laws, Plaintiffs and Class Members are entitled to recover compensatory damages, restitution, punitive and special damages including but not limited to treble damages, reasonable attorneys' fees and costs and other injunctive or declaratory relief as deemed appropriate or permitted pursuant to the relevant law.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(On Behalf of Plaintiffs and All Class Members)

122. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

123. Defendants provided the Plaintiffs and Class Members with an express warranty in the form of written affirmations of fact promising and representing that the Products provide "natural relief" for the ailments for which they are marketed and sold.

124. The above affirmations of fact were not couched as "belief" or "opinion," and were not "generalized statements of quality not capable of proof or disproof."

125. These affirmations of fact became part of the basis for the bargain and were material to the Plaintiffs' and Class Members' transactions.

126. Plaintiffs and Class Members reasonably relied upon Defendants' affirmations of fact and justifiably acted in ignorance of the material facts omitted or concealed when they decided to buy Defendants' Products.

127. Within a reasonable time after they knew or should have known of Defendants' breach, Plaintiff, on behalf of herself and Class Members, placed Defendants on notice of their breach, giving Defendants an opportunity to cure their breach, which they refused to do.

128. Defendants breached the express warranty because the Products do not provide relief from the ailments for which they are marketed and sold and are not natural.

129. Defendants thereby breached the following state warranty laws:

a. Code of Ala. § 7-2-313;

b. Alaska Stat. § 45.02.313;

c. A.R.S. § 47-2313;

d. A.C.A. § 4-2-313;

e. Cal. Comm. Code § 2313;

f. Colo. Rev. Stat. § 4-2-313;

g. Conn. Gen. Stat. § 42a-2-313;

h. 6 Del. C. § 2-313;

i. D.C. Code § 28:2-313;

j. Fla. Stat. § 672.313;

k. O.C.G.A. § 11-2-313;

l. H.R.S. § 490:2-313;

m. Idaho Code § 28-2-313;

n. 810 I.L.C.S. 5/2-313;

o. Ind. Code § 26-1-2-313;

p. Iowa Code § 554.2313;

q. K.S.A. § 84-2-313;

r. K.R.S. § 355.2-313;

s. 11 M.R.S. § 2-313;

t. Md. Commercial Law Code Ann. § 2-313;

u. 106 Mass. Gen. Laws Ann. § 2-313;

v. M.C.L.S. § 440.2313;

w. Minn. Stat. § 336.2-313;

x. Miss. Code Ann. § 75-2-313;

y. R.S. Mo. § 400.2-313;

z. Mont. Code Anno. § 30-2-313;

aa. Neb. Rev. Stat. § 2-313;

bb. Nev. Rev. Stat. Ann. § 104.2313;

cc. R.S.A. 382-A:2-313;

dd. N.J. Stat. Ann. § 12A:2-313;

ee. N.M. Stat. Ann. § 55-2-313;

ff. N.Y. U.C.C. Law § 2-313;

gg. N.C. Gen. Stat. § 25-2-313;

hh. N.D. Cent. Code § 41-02-30;

ii. II. O.R.C. Ann. § 1302.26;

jj. 12A Okl. St. § 2-313;

kk. Or. Rev. Stat. § 72-3130;

ll. 13 Pa. Rev. Stat. § 72-3130;

mm. R.I. Gen. Laws § 6A-2-313;

nn. S.C. Code Ann. § 36-2-313;

oo. S.D. Codified Laws, § 57A-2-313;

pp. Tenn. Code Ann. § 47-2-313;

qq. Tex. Bus. & Com. Code § 2.313;

rr. Utah Code Ann. § 70A-2-313;

ss. 9A V.S.A. § 2-313;

tt. Va. Code Ann. § 59.1-504.2;

uu. Wash. Rev. Code Ann. § 6A.2-313;

vv. W. Va. Code § 46-2-313;

ww. Wis. Stat. § 402.313;

xx. Wyo. Stat. § 34.1-2-313.

130. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs and Class Members were damaged in the amount of the price they paid for the Products, in an amount to be proven at trial.

FIFTH CAUSE OF ACTION
VIOLATION OF THE MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301 et seq.
(On Behalf of Plaintiffs and All Class Members)

131. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

132. Plaintiffs bring this claim individually and on behalf of all members of the Class. Upon certification, the Class will consist of more than 100 named Plaintiffs.

133. The Magnuson-Moss Warranty Act provides a federal remedy for consumers who have been damaged by the failure of a supplier or warrantor to comply with any obligation under a written warranty or implied warranty, or other various obligations established under the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq*.

134. The Product is a "consumer product" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(1).

135. Plaintiffs and other members of the Class are "consumers" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(3).

136. Each of the Defendants is a "supplier" and "warrantor" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301(4) & 2301(5).

137. Defendants represented in writing that the Products provide "natural relief" for the ailments for which they are marketed and sold.

138. These statements were made in connection with the sale of the Products and relate to the nature of the Products and affirm and promise that the Products are as represented and defect free and, as such, are "written warranties" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(6)(A).

139. As alleged herein, Defendants breached the written warranty by selling consumers Products that do not provide relief from the ailments for which they are marketed and sold and are not natural

140. The Products do not conform to the Defendants' written warranty and therefore violate the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq*. Consequently, Plaintiffs and the other members of the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE
(On Behalf of Plaintiffs and All Class Members)

141. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

142. Plaintiffs and Class Members bought the Defendants' Products with the specific purpose of buying products that provide "natural relief" for the ailments for which they are marketed and sold.

143. Defendants knew or had reason to know that the Plaintiffs and other Class Members were buying their Products with the specific purpose of buying products that provide "natural relief" for the ailments for which they are marketed and sold.

144. Plaintiffs and the other Class Members relied on the Defendants in selecting their Products to fit their specific intended use.

145. Defendants held themselves out as having particular knowledge of the Defendants' Products' ingredients and safety.

146. Plaintiffs' and Class Members' reliance on Defendants in selecting Defendants' Products to fit their particular purpose was reasonable given Defendants' claims and

representations in its advertising, packaging and labeling concerning the Products' ingredients and safety.

147. Plaintiffs and the other Class Members' reliance on Defendants in selecting Defendants' Products to fit their particular use was reasonable given Defendants' particular knowledge of the Products it manufactures and distributes.

148. As a result of the foregoing, Plaintiffs and Class Members have been damaged in the amount paid for the Defendants' Products, together with interest thereon from the date of purchase.

SEVENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(On Behalf of Plaintiffs and All Class Members)

149. Plaintiffs repeat and reallege each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

150. Defendants, directly, or through their agents and employees, made false representations, concealments, and non-disclosures to Plaintiffs and Class Members about the Products.

151. In making these false, misleading, and deceptive representations and omissions, Defendants knew and intended that consumers would pay a premium for all products labeled as providing "natural relief" for the ailments for which they are marketed and sold, furthering Defendants' private interest of increasing sales for its Products and decreasing sales of products that are truthfully marketed and sold by Defendants' competitors.

152. As an immediate, direct, and proximate result of Defendants' false, misleading, and deceptive statements and representations, Defendants injured Plaintiffs and Class Members in that they paid a premium price for the Products which were not as represented.

153. In making the representations of fact to Plaintiffs and Class Members described herein, Defendants have failed to fulfill their duties to disclose material facts about the Products. The failure to disclose the true nature of the Products' ingredients was caused by Defendants' negligence and carelessness.

154. Defendants, in making these misrepresentations and omissions, and in doing the acts alleged above, knew or reasonably should have known that the misrepresentations were not true. Defendants made and intended the misrepresentations to induce the reliance of Plaintiffs and Class Members.

155. The Plaintiffs and Class Members relied on these false representations and non-disclosures by Defendants when purchasing the Products, upon which reliance was justified and reasonably foreseeable.

156. As a result of Defendants' wrongful conduct, Plaintiffs and Class Members have suffered and continue to suffer economic losses and other general and specific damages, including amounts paid for the Products and any interest that would have been accrued on these monies, all in the amount to be determined at trial.

EIGHTH CAUSE OF ACTION
COMMON LAW UNJUST ENRICHMENT
(On Behalf of Plaintiffs and All Class Members in the Alternative)

157. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

158. Plaintiffs, on behalf of herself and consumers nationwide, brings a common law claim for unjust enrichment.

159. Defendants' conduct violated, *inter alia*, state and federal law by manufacturing, advertising, marketing, and selling their Products while misrepresenting and omitting material facts.

160. Defendants' unlawful conduct as described in this Complaint allowed Defendants to knowingly realize substantial revenues from selling the Products at the expense of, and to the detriment or impoverishment of, Plaintiffs and Class Members, and to Defendants' benefit and enrichment. Defendants have thereby violated fundamental principles of justice, equity, and good conscience.

161. Plaintiffs and Class Members conferred significant financial benefits and paid substantial compensation to Defendants for Products that were not as Defendants represented them to be.

162. Under the common law principles of unjust enrichment, it is inequitable for Defendants to retain the benefits conferred by Plaintiffs' and Class Members' overpayments.

163. Plaintiffs and Class Members seek disgorgement of all profits resulting from such overpayments and establishment of a constructive trust from which Plaintiffs and Class Members may seek restitution.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues.

WHEREFORE, Plaintiffs, on behalf of herself and the Class, prays for judgment as follows:

(a) Declaring this action to be a proper class action and certifying Plaintiffs as the representative of the Class under Rule 23 of the FRCP;

(b) Entering preliminary and permanent injunctive relief against Defendants, directing Defendants to correct their practices and to comply with consumer protection statutes nationwide, including New York consumer protection law;

(c) Awarding monetary damages, including treble damages;

(d) Awarding punitive damages;

(e) Awarding Plaintiffs and Class Members their costs and expenses incurred in this action, including reasonable allowance of fees for Plaintiffs' attorneys and experts, and reimbursement of Plaintiffs' expenses; and

(f) Granting such other and further relief as the Court may deem just and proper.

Dated: January 12, 2016

THE SULTZER LAW GROUP, P.C.

By: _____

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